

# **Report of the Commissioners of Public Health and the Office of Health Care Access to the Public Health Committee on Outpatient Surgical Facilities**

## **Introduction**

This report is presented to the Public Health Committee in fulfillment of the requirements of Public Act 03-274, "An Act Concerning Outpatient Surgical Facilities". Public Act 03-274 provides new standards governing both for the operation of existing facilities and the development of new facilities. Key provisions of the Public Act include the following:

Outpatient surgical facilities are defined in terms of the level of anesthesia provided. Any provider, including physician office-based surgical practices, using moderate or deep sedation, moderate or deep analgesia or general anesthesia, is now included in the definition of an outpatient surgical facility.

An outpatient surgical facility may operate without a license until March 30, 2007, if it meets the following criteria:

- The outpatient surgical facility provides satisfactory evidence to OHCA that it was in operation on or before July 1, 2003.
- Any outpatient surgical facility that is established between July 1, 2003 and July 1, 2004 requires a CON from OHCA.

The Commissioner of Public Health may grant waivers of the Regulations of Connecticut State Agencies governing outpatient surgical facilities for physical plant and staffing requirements provided such waivers will not infringe upon the health, safety or welfare of patients.

The definition of health care institution is modified to include outpatient surgical facilities.

The Commissioners of OHCA and Department of Public Health shall convene a task force to review laws and regulations governing outpatient surgical facilities. The task force is to include representatives of the Connecticut Hospital Association and the Connecticut State Medical Society, among others. The Commissioners are to submit a report to the Public Health Committee by January 1, 2004 containing the findings and recommendations of the task force.

A copy of the Public Act is included as Attachment 1.

## Outpatient Surgical Facilities Advisory Committee

The Office of Health Care Access and the Department of Public Health convened the Outpatient Surgical Facilities Advisory Committee meeting on September 19, 2003. The purpose of the Advisory Committee was to review laws, regulations, standards, policies and practices, analyze alternatives and formulate recommendations in order to ensure continuation of patient access to and safe operation of all outpatient surgical facilities.

The membership of the group included the following persons:

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| Mary M. Heffernan, Commissioner                      | Office of Health Care Access                   |
| Norma Gyle, R.N., Ph.D., Acting Commissioner         | Department of Public Health                    |
| Richard Amione, APRN, CRNA                           | Wilton Anesthesia                              |
| Karen Buckley-Bates, Legislative Liaison             | Department of Public Health                    |
| Representative Mary Ann Carson, Ranking Member       | Public Health Committee                        |
| Susan Cole, CON Supervisor                           | Office of Health Care Access                   |
| Representative Art J. Feltman, Chairman              | Public Health Committee                        |
| Francisco O. Rivera Ferrer, M.D.                     |  |
| Wendy Furniss, Chief of Bureau of Healthcare Systems | Department of Public Health                    |
| Jeffrey B. Gross, M.D., President                    | Connecticut State Society of Anesthesiologists |
| Jennifer Jackson, President                          | Connecticut Hospital Association               |
| Edward Kamens, M.D.                                  |  |
| Alden Mead   | EYE Center                                     |
| Kristian Mineau                                      | Constitution Eye Surgery Center                |
| Patrick Monahan, Esquire                             | Connecticut Hospital Association               |
| Senator Christopher S. Murphy, Chairman              | Public Health Committee                        |
| Joseph Oros, Legislative Liaison                     | Department of Public Health                    |
| Gary Price, M.D.                                     | Connecticut State Medical Society              |
| Jan Szigeti, Administrator                           | HEALTHSOUTH Surgery Center of Danbury          |
| Jef Wolter, Esquire                                  | Updike, Kelly & Spellacy, P.C.                 |

Meetings were held on September 19, 2003, October 3, 2003, October 17, 2003 and October 31, 2003. In order to facilitate the work of the OSF Advisory Committee, the agenda of each meeting was focused on a specific topic related to the implementation of the Public Act. The meeting held on September 19<sup>th</sup> was the introductory meeting, the October 3<sup>rd</sup> meeting discussed potential changes to OHCA's statutes and the CON process, the October 17<sup>th</sup> meeting discussed potential changes to DPH statutes and the Public Health Code, and the October 31<sup>st</sup> meeting focused on a discussion of health care policies and recommendations. Copies of the minutes of each of the meetings are included as Attachment 2.

## OHCA Statutes and Regulations

The Outpatient Surgical Facilities Advisory Committee work group discussed a number of significant issues and themes related to the CON process. The following is an examination of the major issues raised by the OSF Advisory Committee work group:

| Major Issues Discussed  | OHCA Responses  |
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| <p><b>Statutory Issues Discussed:</b></p> <p>Section 19a-630, C.G.S. The term “free standing” should be removed from outpatient surgical facility.</p> <p>Section 19a-637, C.G.S. Many of the principles and guidelines are not relevant and should be deleted from the statute, such as those relating to the State Health Plan, teaching and research responsibilities, and patient/physician mix.</p> <p>Section 19a-638, C.G.S.</p> <ul style="list-style-type: none"> <li>o This section requires CON review for changes to all or part of the ownership or control of a facility. Does the addition or removal of a partner trigger CON review under the requirements of the statute (i.e., does it require a CON)?</li> <li>o Does the termination of a doctor’s practice that includes an OSF require a CON?</li> </ul> <p>Section 19a-639, C.G.S. If a doctor moves an office that has an attached OSF, does this move trigger CON review?</p> | <p>The statute can be modified to remove the term free standing from this section.</p> <p>OHCA is required to make written findings related to each of the principles and guidelines. OHCA agrees that they may not always be relevant and that Not Applicable may sometimes be an appropriate finding.</p> <p>OHCA generally requires CON review if a majority of the ownership or control of a health care facility is changed. The addition or removal of a partner usually does not trigger CON review in most cases. OHCA plans to address and alleviate this concern with its 2004 legislative proposals.</p> <p>OHCA will seek to have the statute modified to require that notification occurs but that a CON not be required.</p> <p>CON review would only occur if new services are proposed, the associated total capital cost exceeds \$1,000,000, or the office is being moved into a new market area.</p> |
| <p><b>Patient Safety Issues:</b></p> <p>If a physician’s office is accredited, then the need for CON is eliminated.</p>   | <p>Accreditation does not address the CON review issues of need, impact on existing providers and accessibility.</p>  |

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| <p><b>Alternative Approaches to the Statutes:</b></p> <p>Some physicians believe that the former approach for single specialty practices was very clear and advocate a return to that regulatory approach.</p> <p>Some physicians advocate consideration of items such as procedure length, capital budget and number of providers as some sort of threshold.</p> <p>Some providers expressed a concern that a formal CON process is too exclusionary, subjective and serves as a barrier.</p> <p>There is a need for regulatory parity among all classes of providers.</p> | <p>The prior CON regulatory approach for single specialty practices is no longer applicable, since OSFs and doctors' offices are doing many more complicated and advanced procedures that impact the financial viability of the health care delivery system. This major change creates a need for an updated CON regulatory approach.</p> <p>The types of procedures, procedure lengths, providers' capital budgets and the number of providers in any given geographic area vary too greatly to be used as thresholds for CON review.</p> <p>The CON process included in Public Act 03-274 and OHCA's 2004 legislative proposals will help to set up a fair delivery system for the consumer and provider, insure the financial viability of the health care delivery system, and develop broader health care planning objectives.</p> <p>The provisions of Public Act 03-274 and OHCA's 2004 legislative proposals will help to facilitate CON regulatory parity among all classes of OSF service providers.</p> |
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## DPH Statutes and Regulations

| Major Issues Discussed  | DPH Responses  |
|---|--|
| <p>Providers identified some surgical procedures do not qualify for reimbursements (e.g. cosmetic); therefore, some consideration regarding licensure requirements should be considered.</p> <p>Credentials of physicians providing surgical procedures in an office-based practice should be specified.</p> <p>Providers believe that most currently operating office-based practices will not meet the regulations governing outpatient surgical facilities.</p> <p>Some physicians expressed concern regarding the delivery of anesthesia in current office-based settings and levels of licensed individuals who may perform such functions when licensure as an institution is required.</p> | <p>DPH licensure requirements are not based upon source of payment.</p> <p>DPH is considering regulatory changes that would mandate board certification in the specified area of practice and/or active hospital privileges.</p> <p>DPH has had extensive experience with addressing waiver requests in regulated entities; however, the prospective licensee must take the responsibility to initiate the licensure process early so that applicable pre-licensure inspections can be made by DPH staff, relative to physical plant requirements that may require waivers of the regulations, and allow for a seamless and timely granting of licensure.</p> <p>DPH has reviewed this concern and believes accommodations are possible for both anesthesiologists and Certified Registered Nurse Anesthetists (CRNAs) within various settings, based upon level of anesthesia and extent of procedures.</p> |

## **Recommendations**

After careful consideration of the major issues discussed by the Outpatient Surgical Facilities Advisory Committee work group, the Commissioners of DPH and OHCA make the following recommendations:

DPH recommends applying its longstanding waiver procedure to written requests received from providers of office-based surgical services (i.e. case-by-case consideration of impact of request on patient health and safety).

OHCA recommends that Section 19a-630, C.G.S. be amended to remove the term free standing from outpatient surgical facility.

OHCA recommends that Section 19a-638, C.G.S. be amended so that the addition or removal of a partner or partners, not constituting a majority of ownership or control of an outpatient surgical facility, will only require notification of OHCA rather than a formal CON review.

Additional concerns will be addressed in greater detail in OHCA's 2004 legislative proposals with regard to outpatient surgical facilities.

**Substitute Senate Bill No. 1148****Public Act No. 03-274****AN ACT CONCERNING OUTPATIENT SURGICAL FACILITIES.**

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective July 1, 2003*) (a) As used in this section and subsection (a) of section 19a-490 of the general statutes, as amended by this act, "outpatient surgical facility" means any entity, individual, firm, partnership, corporation, limited liability company or association, other than a hospital, engaged in providing surgical services for human health conditions that include the use of moderate or deep sedation, moderate or deep analgesia or general anesthesia, as such levels of anesthesia are defined from time to time by the American Society of Anesthesiologists, or by such other professional or accrediting entity as recognized by the Department of Public Health.

(b) No entity, individual, firm, partnership, corporation, limited liability company or association, other than a hospital, shall individually or jointly establish or operate an outpatient surgical facility in this state without complying with chapter 368z of the general statutes and obtaining a license from the Department of Public Health for such facility pursuant to the provisions of chapter 368v of the general statutes, unless such entity, individual, firm, partnership, corporation, limited liability company or association meets any of the following exceptions: (1) Provides to the Office of Health Care Access satisfactory evidence that it was in operation on or before July 1, 2003; (2) obtains, on or before July 1, 2003, from the Office of Health Care Access, a determination that a certificate of need is not required and provides the office with satisfactory evidence that it has commenced development of an outpatient surgical facility prior to July 1, 2003; or (3) obtains, between July 1, 2003, and June 30, 2004, inclusive, a certificate of need from the office in accordance with the policies and procedures utilized by the office in approving certificates of need as of July 1, 2003. If an entity, individual, firm, partnership, corporation, limited liability company or association satisfies any of the exceptions in this subsection, it may operate an outpatient surgical facility without a license through March 30, 2007, and shall have until March 30, 2007, to obtain a license from the Department of Public Health. No outpatient surgical facility may be established between July 1, 2003, and July 1, 2004, unless it satisfies one of the exceptions in this subsection.

(c) The factors to be considered by the Commissioner of Health Care Access in making a determination pursuant to subdivision (2) of subsection (b) of this section as to whether

development of an outpatient surgical facility has been commenced shall include, but need not be limited to, whether the applicant for such determination has (1) contractually committed to a site for a facility, (2) expended significant funds for predevelopment expenses for the facility, such as consultation and equipment purchases, or (3) entered into contractual arrangements with third-party payors for services related to the operation of the facility. If any application for a determination pursuant to subdivision (2) of subsection (b) of this section is denied, the applicant may request that such denial be reviewed and reconsidered by the commissioner. The commissioner shall give notice of the grounds for such denial and shall conduct a hearing concerning such denial in accordance with the provisions of chapter 54 of the general statutes concerning contested cases.

(d) Notwithstanding the provisions of this section, each outpatient surgical facility shall continue to be subject to the obligations and requirements applicable to such facility, including, but not limited to, any applicable provision of chapter 368v or 368z of the general statutes.

(e) The provisions of this section shall not apply to persons licensed to practice dentistry or dental medicine pursuant to chapter 379 of the general statutes or to outpatient clinics licensed pursuant to chapter 368v of the general statutes.

(f) Any outpatient surgical facility that is accredited as provided in section 19a-691 of the general statutes, shall continue to be subject to the requirements of section 19a-691 of the general statutes.

(g) On and after July 1, 2004, any entity, individual, firm, partnership, corporation, limited liability company or association that meets the definition of outpatient surgical facility pursuant to subsection (a) of this section, shall be subject to the rights and obligations that exist under statutes in effect as of June 30, 2003, and nothing in this section shall be used or introduced in any proceeding to suggest or infer or otherwise indicate or imply that such entity, individual, firm, partnership, corporation, limited liability company or association is or is not a free standing outpatient surgical facility under section 19a-630 of the general statutes. No implication shall be created by this section, or used in any manner in any proceeding of any kind, as to whether or not a certificate of need is required on or after July 1, 2004.

(h) The Commissioner of Public Health may provide a waiver for outpatient surgical facilities from the physical plant and staffing requirements of the licensing regulations adopted pursuant to chapter 368v of the general statutes, provided no waiver may be granted unless the health, safety and welfare of patients is ensured.

Sec. 2. Subsection (a) of section 19a-490 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2003*):

(a) "Institution" means a hospital, residential care home, health care facility for the handicapped, nursing home, rest home, home health care agency, homemaker-home health aide agency, mental health facility, substance abuse treatment facility, [outpatient surgical facility](#), an infirmary operated by an educational institution for the care of students enrolled in,



and faculty and employees of, such institution; a facility engaged in providing services for the prevention, diagnosis, treatment or care of human health conditions, including facilities operated and maintained by any state agency, except facilities for the care or treatment of mentally ill persons or persons with substance abuse problems; and a residential facility for the mentally retarded licensed pursuant to section 17a-227 and certified to participate in the Title XIX Medicaid program as an intermediate care facility for the mentally retarded.

Sec. 3. (*Effective from passage*) The Commissioners of Health Care Access and Public Health shall develop an advisory committee for the purpose of reviewing laws, regulations, standards, policies and practices, analyzing alternatives and formulating recommendations with regard to the issues surrounding the licensure and regulation of outpatient surgical facilities in order to ensure continuation of patient access to and safe operation of such facilities. Such committee shall include the presidents of the Connecticut Hospital Association and the Connecticut State Medical Society, or their designees, and may include representatives from hospitals, physicians, patients, and such other members as the commissioners shall deem necessary. On or before January 1, 2004, the commissioners shall submit a report, in accordance with section 11-4a of the general statutes, to the joint standing committee of the General Assembly having cognizance of matters relating to public health containing the findings and recommendations of the committee, if any.

Approved June 26, 2003

## Minutes

### Outpatient Surgical Facilities (OSF) Advisory Committee September 19, 2003

The meeting of the Outpatient Surgical Facilities Advisory Committee meeting was held on Friday, September 19, 2003 at 410 Capitol Avenue, OHCA Hearing Room. Present at the meeting:

Work Group Members Present: Commissioner Mary M. Heffernan; Acting Commissioner Norma Gyle, R.N., Ph.D.; Representative Mary Ann Carson; Senator Christopher S. Murphy; Richard Amione, APRN, CRNA; Susan Cole; Francisco O. Rivera Ferrer, M.D.; Wendy Furniss; Jeffery B. Gross; M.D.; Edward Kamens, M.D.; Kris Mineau; Patrick Monahan; Joseph Oros; Gary Price, M.D.; Jan Szigeti; and Jef Wolter.

In Attendance: Abby Ahlborn, Ken Ferrucci, Amy Hanaburgh, Kevin Kinsella, Courtney Larkin, Bill Malitsky, Alden Mead, Karen Weeks, and Lisa Winkler.

OHCA staff: John Blair and Harold M. Oberg.

| Agenda Item             | Discussion  | Action         |
|-------------------------|---|----------------|
| 1. Introductory Remarks | <p>Commissioner Heffernan opened the meeting by introducing herself and Acting Commissioner Norma Gyle. Commissioner Heffernan stated that the charge of the OSF Advisory Committee was set forth in Section 3 of Public Act Number 03-274 and includes the following:</p> <ul style="list-style-type: none"><li>• Review laws, regulations, standards, policies, and practices, analyze alternatives and formulate recommendation in order to ensure continuation of patient access to and safe operation of such facilities</li><li>• The Commissioners shall submit a report to the joint standing committee of the General Assembly having cognizance of matters relating to public health containing the findings and recommendations of the OSF Committee on or before January 1, 2004.</li></ul> <p>The members of the OSF Advisory Committee were introduced.</p> | None required. |

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| 2. Legislative Intent             | <p>Senator Christopher Murphy discussed the legislative intent of Public Act 03-274 and stated that the law was designed to:</p> <ul style="list-style-type: none"> <li>• Set up a fair delivery system for both the consumer and provider</li> <li>• Insure the existence of a safe system</li> <li>• Establish parameters for licensure</li> <li>• Insure financial viability of the health care delivery system</li> </ul> <p>Commissioner Heffernan discussed the time constraints associated with the delivery of a report on January 1, 2004. In order to meet the statutory deadline, the work of the OSF must be concluded by mid-November.</p> | None required  |
| 3. Committee Members Input        | <p>General discussion occurred on issues related to the following:</p> <ul style="list-style-type: none"> <li>• Continued operation of existing office based surgical facilities</li> <li>• Development of a regulatory scheme</li> <li>• Moving forward, the development of broader health care planning.</li> </ul>   | None required.   |
| 4. Next meeting time and location | <b>The next meeting will be held on October 3, 2003 at 1p.m. in the OHCA hearing room, 340 Capitol Avenue, Hartford</b>   | Hearing notice and charge to members will be prepared. |

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## Minutes

### Outpatient Surgical Facilities (OSF) Advisory Committee October 3, 2003

The meeting of the Outpatient Surgical Facilities Advisory Committee meeting was held on Friday, October 3, 2003 at 1:00 pm at 410 Capitol Avenue, OHCA Hearing Room. Present at the meeting:

Work Group Members Present: Commissioner Mary M. Heffernan; Acting Commissioner Norma Gyle, R.N., Ph.D.; Representative Mary Ann Carson; Representative Art J. Feltman; Richard Amione, APRN, CRNA; Karen Buckley-Bates, Susan Cole; Francisco O. Rivera Ferrer, M.D.; Wendy Furniss; Jeffery B. Gross; M.D.; Edward Kamens, M.D.; Alden Mead, Kristian Mineau; Patrick Monahan; Joseph Oros; Gary Price, M.D.; and Jef Wolter.

In Attendance: Abby Ahlborn, Ken Ferrucci, Layne Gallos, Courtney Larkin, Kyra Nesteriak, Lori Samele, and Karen Weeks

OHCA staff: John Blair and Harold M. Oberg.

| Agenda Item             | Discussion   | Action        |
|-------------------------|--|---------------|
| 1. Introductory Remarks | <p>Commissioner Heffernan opened the meeting.</p> <ul style="list-style-type: none"><li>• Alden Mead, the newest member of the OSF Advisory Committee was introduced.</li><li>• Commissioner Heffernan indicated that the purpose of today's meeting was to discuss OHCA's statutes and regulations, particularly those related to the CON process, as they relate to office based surgical facilities. The OSF Advisory Committee is interested in receiving recommendations. She requested that any discussion related to quality and the public health code be held to the next meeting when the meeting topic is Department of Public Health statutes and regulations.</li></ul> | None required |

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| <p>2. Discussion of OHCA (CON) Regulations</p> | <p>Discussion occurred on issues related to OHCA's CON statutes and regulations as follows:</p> <ul style="list-style-type: none"> <li>• Sections 19a-630, 19a-637, 19a-638 and 19a-639 need to be examined to determine whether or not they need to be modified in order to address issues of definition, ownership, initiation and termination of services, and relevance of review criteria.</li> <li>• The review criteria need to be clearly specified.</li> <li>• Some committee members expressed concern that the CON process is exclusive, expensive, and subjective.</li> <li>• Some committee members wish to develop a separate licensure category for OSF.</li> <li>• Some committee members wish to develop a waiver to CON that is similar to the single specialty approach that was previously employed.</li> <li>• Some committee members believe that the current statutes and regulations are adequate and that new regulations are not required for OSFs.</li> </ul> | <p>Representative Carson suggested that the OSF advisory committee members form a subcommittee to develop recommendations.</p>   |
| <p>3. Next meeting time and location</p>       | <p><b>The next meeting will be held on October 17, 2003 at 1 p.m. in the OHCA hearing room, 410 Capitol Avenue, Hartford.</b></p>  | <p><b>Copies of DPH Regulations were distributed to the OSF Advisory Committee members. Members should review these regulations and be prepared to present recommendations regarding potential changes to physical plant and staffing regulations.</b></p> |

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## Minutes

### Outpatient Surgical Facilities (OSF) Advisory Committee October 17, 2003

The meeting of the Outpatient Surgical Facilities Advisory Committee meeting was held on Friday, October 17, 2003 at 410 Capitol Avenue, OHCA Hearing Room. Present at the meeting:

Work Group Members Present: Commissioner Mary M. Heffernan; Richard Amione, APRN, CRNA; Francisco O. Rivera Ferrer, M.D.; Jeffrey Gross, M.D.; Edward Kamens, M.D.; Kris Mineau; Alden Mead; Patrick Monahan; Gary Price, M.D.; Jan Szigeti; and Jef Wolter.

In Attendance: Abby Ahlborn; Tricia Dinneen Priebe; Ken Ferrucci; Deb Hutton; John Newman, Esq.; Lori Samele; Karen Weeks, and Lisa Winkler.

OHCA staff: John Blair, Harold M. Oberg

DPH staff: Warren Wollschlager, Karen Buckley-Bates, Wendy Furniss

| Agenda Item                                   | Discussion  | Action         |
|---|---|----------------|
| 1. Introductory Remarks                       | Commissioner Heffernan opened the meeting. <ul style="list-style-type: none"><li>Commissioner Heffernan indicated that the purpose of today's meeting was to discuss the Department of Public Health's statutes and regulations.</li></ul>  | None required. |
| 2. Discussion of DPH Statutes and Regulations | Warren Wollschlager, Chief of Staff, DPH, noted that the Department wanted to allow sufficient time to hear all committee members' comments, so the meeting today would be a listening session, rather than a discussion. The Department will then utilize the comments, as appropriate, as it implements DPH's responsibilities under P.A. 03-274. | None required  |

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| 3. Committee Members Input        | <p>General discussion occurred on issues related to the following:</p> <ul style="list-style-type: none"> <li>• Current DPH requirements (19-13-D56) for freestanding surgical centers: particularly physical plant, administrative, staffing.</li> <li>• Waivers v. new set of regulations.</li> <li>• Principles of the American College of Surgeons – quality standards.</li> <li>• Accreditation standards, possibly in lieu of regulations.</li> <li>• Other state's regulations, e.g. Rhode Island.</li> <li>• Role of the Certified Registered Nurse Anesthetist (CRNA).</li> <li>• No overnight stay or other lengthy procedures in office setting.</li> </ul> | None required.   |
| 4. Next meeting time and location | <b>The next meeting will be held on October 31, 2003 at 11:00 a.m. in the OHCA Hearing Room, 340 Capitol Avenue, Hartford</b>  | Hearing notice and charge to members will be prepared. |

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